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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,268	01/20/2004	Huai-Jen Tsai	8961-000009/US	6868

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EXAMINER

BERTOGLIO, VALARIE E

ART UNIT PAPER NUMBER

1632

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/759,268	TSAI, HUI-JEN	
	<b>Examiner</b>	<b>Art Unit</b>	
	Valarie Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-12 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, drawn to a recombinant plasmid comprising a ubiquitous promoter operably linked to a fluorescent gene and a skin-specific promoter operably linked to another fluorescent gene, classified in class 536, subclass 23.1.
- II. Claims 1-4, drawn to a recombinant plasmid comprising a ubiquitous promoter operably linked to a fluorescent gene and a muscle-specific promoter operably linked to another fluorescent gene, classified in class 536, subclass 23.1.
- III. Claims 5-9, drawn to a method of producing a transgenic fish using a recombinant plasmid comprising a ubiquitous promoter operably linked to a fluorescent gene and a skin-specific promoter operably linked to another fluorescent gene and the fish, classified in class 800,800, subclass 21,20.
- IV. Claims 5-9, drawn to a method of producing a transgenic fish using a recombinant plasmid comprising a ubiquitous promoter operably linked to a fluorescent gene and a muscle-specific promoter operably linked to another fluorescent gene and the fish, classified in class 800,800, subclass 21,20.
- V. Claims 10-12, drawn to a method of producing a transgenic fish using two fragments of a recombinant plasmid a first fragment comprising a ubiquitous promoter operably linked to a fluorescent gene and a second fragment comprising a skin-specific promoter operably linked to another fluorescent gene, classified in class 800, subclass 20.

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VI. Claims 10-12, drawn to a method of producing a transgenic fish using two fragments of a recombinant plasmid a first fragment comprising a ubiquitous promoter operably linked to a fluorescent gene and a second fragment comprising a muscle-specific promoter operably linked to another fluorescent gene, classified in class 800, subclass 20.

It is noted that claim 3 lists both muscle-specific promoters and skin-specific promoters.

If Applicant elects Group I, claim 3 will be examined to the extent that it reads on S-100 and cytokeratin type II C. If Applicant elects Group II, claim 3 will be examined to the extent that it reads on  $\alpha$ -actin, troponin T, Troponin T and myosin heavy chain.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct. Invention I is drawn to a plasmid comprising a skin-specific promoter that drives gene expression in skin. Invention II is drawn to a plasmid comprising a muscle-specific promoter that drives gene expression in muscle. The plasmids have different structure, function and purpose. It would require an undue burden to search Inventions I and II together.

Invention I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the gene fragment of Invention I can be used to make recombinant cells or as a DNA probe in addition to use in the method of Invention III.

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Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Invention I has a different design, mode and effect from the transgenic fish of Invention IV. The plasmid of Invention I has a skin specific promoter whereas the plasmid used to make the fish of Invention IV has a muscle specific promoter. The plasmid of Invention I is not used in making or carrying out the methods of Invention IV. The Inventions are classified differently. It would require an undue burden to search Inventions I and IV together.

Invention I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the gene fragment of Invention I can be used to make recombinant cells or as a DNA probe or in the method of Invention III that is distinct from that of Invention V.

Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Invention I has a different design, mode and effect from the transgenic fish of Invention VI. The plasmid of Invention I has a skin specific promoter whereas the plasmid used to make the fish of Invention IV has a muscle specific promoter. The plasmid of Invention I is not used in making or carrying out the methods

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of Invention VI. The Inventions are classified differently. It would require an undue burden to search Inventions I and VI together.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Invention II has a different design, mode and effect from the transgenic fish of Invention III. The plasmid of Invention II has a muscle specific promoter whereas the plasmid used to make the fish of Invention III has a skin specific promoter. The plasmid of Invention II is not used in making or carrying out the methods of Invention III. The Inventions are classified differently. It would require an undue burden to search Inventions II and III together.

Invention II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the gene fragment of Invention II can be used to make recombinant cells or as a DNA probe in addition to use in the method of Invention IV.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Invention II has a different design, mode and effect from the transgenic fish of Invention V. The plasmid of Invention II has a muscle specific promoter whereas the plasmid used to make the fish of Invention V has a skin specific promoter. The plasmid of Invention II is not used in making or carrying out the methods

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of Invention V. The Inventions are classified differently. It would require an undue burden to search Inventions II and V together.

Invention II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the gene fragment of Invention II can be used to make recombinant cells or as a DNA probe or in the method of Invention IV that is distinct from that of Invention VI.

Inventions III and IV are patentably distinct because they are drawn to methods of making transgene fish that have different structure and function. The fish of each invention require promoters specifically expressed in distinct tissues, skin and muscle. The fish would have different uses. It would require an undue burden to search Inventions III and IV together.

Inventions III and V are patentably distinct because they are drawn to methods of making transgene fish that have different structure and function. The fish of each invention comprise different transgenes. The fish of Invention III comprise a single transgene whereas the fish of Invention V comprise two separate unlinked transgenes. The fish have different uses. It would require an undue burden to search Inventions III and V together.

Inventions III and VI are patentably distinct because they are drawn to methods of making transgene fish that have different structure and function. The fish of each invention require promoters specifically expressed in distinct tissues, skin and muscle. Furthermore, the ubiquitously expressed gene is linked to the skin specific gene in the fish of Invention III

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whereas the genes are not genetically linked in the fish of Invention VI. The fish would have different uses. It would require an undue burden to search Inventions IV and VI together.

Inventions IV and V are patentably distinct because they are drawn to methods of making transgene fish that have different structure and function. The fish of each invention require promoters specifically expressed in distinct tissues, skin and muscle. Furthermore, the ubiquitously expressed gene is linked to the muscle specific gene in the fish of Invention IV whereas the genes are not genetically linked in the fish of Invention V. The fish would have different uses. It would require an undue burden to search Inventions IV and VI together.

Inventions IV and VI are patentably distinct because they are drawn to methods of making transgene fish that have different structure and function. The fish of each invention comprise different transgenes. The fish of Invention IV comprise a single transgene whereas the fish of Invention VI comprise two separate unlinked transgenes. The fish have different uses. It would require an undue burden to search Inventions IV and VI together.

Inventions V and VI are patentably distinct because they are drawn to methods of making transgene fish that have different structure and function. The fish of each invention require promoters specifically expressed in distinct tissues, skin and muscle. The fish would have different uses. It would require an undue burden to search Inventions V and VI together.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §



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**821.04. Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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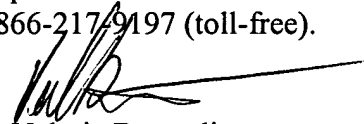
Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Valarie Bertoglio  
Examiner  
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